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ADDENDUM FOR 2-CHLOROPHENOL

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OFFICE OF WATER REGULATIONS
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Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority Pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five jears. These addenda represent an updated literature search current as of 1988, plus additional information form Agency files and Program Offices. This addendum is to update the existing Ambient Water Quality Criteria Document for 2-Chlorophenol.

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PREFACE

Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information from Agency files and Program Offices. The first draft of this addendum was prepared by Syracuse Research Corporation under contract no. 68-C8-0004.

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LIST OF ABBREVIATIONS

BCF	Bioconcentration factor
CRAVE	Carcinogen Risk Assessment Verification Endeavor
LOAEL	Lowest-observed-adverse-effect level
NOAEL	No-observed-adverse-effect level
ppm	Parts per million
RfD	Reference dose

INTRODUCTION

Under Section 304(a)(1) of the Clean Water Act of 1977 as amended in 1987, the U.S. EPA is required to publish criteria for water quality accurately reflecting the latest scientific knowledge regarding the effects on health and welfare that may occur from the presence of pollutants in any body of water, including groundwater. In accordance with the 1977 act, Ambient Water Quality Criteria Documents (AWQCDs) were developed in 1980 for 65 toxic pollutants or classes of pollutants listed under Section 307(a)(1).

These addenda are intended to serve as an update of the original AWQCDs. The addenda provide the Agency with the latest scientific assessments of potential health hazards associated with these pollutants and serve as guidelines for modifying the current (1980) AWQCDs.

The human health criteria in these addenda are based on Agency verified risk assessment values when available. These values consist of reference doses (RfD) for those chemicals believed to be systemic toxicants (i.e., do not induce cancer) and cancer risk factors for those thought likely to cause cancer in humans. The verification process consists of a review and consensus of risk assessment values provided by an Agency workgroup consisting of scientists from each of the major Agency offices. Assessments for noncarcinogens are verified by the RfD workgroup and those for carcinogens are verified by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) workgroup. If such values are not available, the criteria are based on the most recent Agency health assessment. In the absence of any appropriate Agency value, RfD values or cancer risk factors are derived by current Agency methods if adequate new data are available, and criteria are recommended based on the proposed RfD or risk factor.

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is derived by dividing a NOAEL or LOAEL for subchronic or chronic exposure by standard uncertainty factor(s) times an additional uncertainty factor:

$$RfD = \frac{\text{NOAEL or LOAEL}}{UF(s) \times UF}$$

The standard uncertainty factors are applied to reflect the various types of data used to estimate RfDs. An uncertainty factor of 10 is used to account for variations in human sensitivity when extrapolating from valid human studies involving long-term exposure of average, healthy subjects. An additional 10-fold factor is used for each of the following: to extrapolate from long-term animal studies to the case of humans, to extrapolate from subchronic animal studies to chronic exposure, and to extrapolate from a LOAEL to a NOAEL. An additional uncertainty factor of >0-10 may be applied to reflect professional assessment of the uncertainties of the study and data base not explicitly addressed by the standard uncertainty factors (i.e., completeness of the overall data base). The default value for the additional uncertainty factor is 1.

In assessing the carcinogenic potential of a chemical, the U.S. EPA classifies the chemical into one of the following groups according to the degree of evidence in epidemiological studies and animal studies: Group A - Human Carcinogen; Group B - Probable Human Carcinogen [limited evidence in humans with or without sufficient evidence in animals (Group B1) or inadequate evidence in humans with sufficient evidence in animals (Group B2)]; Group C - Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); Group D - Not Classifiable as to

Human Carcinogenicity (inadequate or no evidence); Group E - Evidence of Noncarcinogenicity for Humans. Quantitative carcinogenic risk assessments are performed for chemicals in Groups A and B, and on a case-by-case basis for chemicals in Group C. Upper-bound cancer unit risks (slope values) are estimated through the use of mathematical extrapolation models. Most commonly for animal data, the linearized multistage model with a 95% upper confidence limit is used to provide a low-dose estimate of cancer risk. The cancer risk is characterized as an upper-limit estimate (i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-limit estimate and in fact may be lower). Alternative risk models to the multistage model, such as the one-hit, Weibull, Logit or Probit model, are available and may be used when the evidence indicates that they may be more appropriate. In the absence of such evidence, the Agency recommends the linearized multistage model to provide consistency of approach and an upper-bound on the potential carcinogenic risk. In the case where human data are used for quantitative risk assessment, an upper-bound estimate rather than a 95% upper-bound estimate is used when low-dose linearity is assumed.

In the development of this Addendum to the AWQCD on 2-chlorophenol, recent Agency assessments have been consulted. A computerized literature search was conducted to cover studies published more recently than the latest Agency assessment (i.e., published in 1987 to 1988). New key studies have been evaluated.

REVIEW OF NEW DATA

Toxicologic/Carcinogenic Effects

New data are available that allow derivation of a criterion level based upon health effects, eliminating the need to rely upon the aesthetic effect [organoleptic data (Dietz and Traud, 1978)] used as the basis for the criterion in the 1980 document (U.S. EPA, 1980). Although no human data regarding health effects of oral exposure to 2-chlorophenol and no conventional studies in animals of the effects of oral doses of 2-chlorophenol on a comprehensive set of parameters of toxicity are available, two reports by Exon and Koller (1982, 1985) provide new pertinent information. Groups of 12-20 weanling female Sprague-Dawley rats were bred after administration of 0, 5, 50 or 500 ppm of 2-chlorophenol in the drinking water for 10 weeks (Exon and Koller, 1982). Treatment was continued through gestation and weaning (3 weeks of age). Parameters evaluated were conception rate, litter size, birth weight, weaning weight, number of stillbirths and weanling hematology (hemoglobin levels, hematocrit, red and white cell counts, and mean corpuscular volume). The effects observed included an increased percent of successful conceptions, a significant increase in percent stillborns and a significant decrease in litter size at 500 ppm 2-chlorophenol.

As part of the same study, groups of eight pups, randomly selected from progeny of dams treated as above, were exposed for an additional 12-15 weeks to the same drinking water concentrations of 2-chorophenol as their dams had received (Exon and Koller, 1985). Toxicity parameters examined were humoral immunity (measured by the enzyme-linked immunosorbent assay), cell-mediated immunity (measured via a delayed-type hypersensitivity reaction to antigens) and macrophage function (evaluated by assessing ability to phagocytize sheep

red blood cells in vitro). No significant effects were noted for these endpoints, but a decreased level of humoral antibody to bovine serum albumin occurred consistently in all treated groups.

Exon and Koller (1985) also conducted a study to evaluate the carcinogenicity/cocarcinogenicity potential of 2-chlorophenol. Groups of 24-32 male and female Sprague-Dawley rats were exposed from ~3 weeks of age through weaning for 24 months to 0, 5, 50 or 500 ppm 2-chlorophenol concentrations in drinking water. Hematologic toxicity parameters were evaluated. At 500 ppm, red blood cell counts, hemoglobin levels and packed cell volumes were significantly increased. Effects at lower doses were not discussed.

Data regarding 2-chlorophenol as a complete carcinogen are limited to the Exon and Koller (1985) study, which gave negative results. Sprague-Dawley rat dams were exposed orally from ~3 weeks of age through breeding, parturition and lactation to 0, 5, 50 or 500 ppm concentrations of 2-chlorophenol in drinking water. Groups of between 24 and 32 progeny of each sex were maintained on the same regimen until death or 24 months of age. No differences between exposed and control animals in tumor incidences, latency to tumor formation or variations in tumor types were found through microscopic examination of major organs.

The Exon and Koller (1985) study also examined the potential synergistic effects of the human carcinogen, ethylnitrosourea, with 2-chlorophenol, and found equivocally positive results. Rat dams selected from each chlorophenol treatment regimen were exposed orally to ethylurea (precursor to ethylnitrosourea) in the diet and to sodium nitrite in the drinking water during days 14-21 of gestation. Offspring were exposed via drinking

water to 2-chlorophenol (starting either prenatally via the dams or postnatally). Tumor incidence increased and time-to-tumor latency decreased in all groups of 2-chlorophenol-exposed males, compared with those exposed to ethylnitrosourea alone. Since a concentration-response relation was not found and no synergistic effects were seen in females, and because there was a high tumor incidence among the ethylnitrosourea-only controls, conclusions regarding this seemingly positive response in males are tentative.

The U.S. EPA (1987) recommended that 2-chlorophenol be assigned carcinogen Group D classification, not classifiable as to human carcinogenicity.

Bioconcentration Factor (BCF)

The bioconcentration data for 2-chlorophenol (U.S. EPA, 1978) used as the basis for the BCF in the 1980 AWQCD have been published by Barrows et al. (1980). There is no change in the measured steady-state BCF of 214 for 2-chlorophenol in bluegill sunfish (U.S. EPA, 1978; Barrows et al., 1980) or to the weighted average BCF of 134 adjusted for the lipid content in the edible portion of the freshwater and estuarine organisms estimated to be consumed by humans (U.S. EPA, 1980).

QUANTIFICATION OF EFFECTS

The U.S. EPA (1980) recommended an ambient water quality criterion for 2-chlorophenol of 0.1 µg/ℓ, based upon organoleptic data. Adequate toxicity data were not available at that time, nor were other standards or guidelines located. It was emphasized that the criterion was based upon aesthetics, not upon health effects.

Other than the Exon and Koller studies (1982, 1985), no subchronic, chronic, carcinogenicity or teratogenicity studies were available that would support or aid in the derivation of criteria for 2-chlorophenol. The new evidence from Exon and Koller (1982) has been selected as the basis for the verified oral RfD (U.S. EPA, 1988). The study reported a LOAEL of 500 ppm, which caused adverse reproductive effects, and identified a NOAEL of 50 ppm. Applying the RfD Workgroup (U.S. EPA, 1988) assumption that a rat drinks a daily amount of water equal to 10% of its body weight, 500 ppm was converted to 50 mg/kg/day, and 50 ppm to 5 mg/kg/day. A verified RfD of 0.005 mg/kg/day was derived using an uncertainty factor of 1000: 10 to account for interspecies extrapolation, 10 for the range of sensitivity within the human population and 10 for the use of data from a subchronic study.

The verified RfD value of 0.005 mg/kg/day can be used to calculate an ambient water quality criterion. Assuming an average human water consumption of 2 ℓ/day, fish consumption of 6.5 g/day, a 70 kg average adult weight and using a BCF of 134 ℓ/kg for 2-chlorophenol, a criterion for consumption of water and fish and shellfish of 0.122 mg/ℓ is calculated. The criterion for consumption of fish and shellfish alone, applying the same assumptions as above, is 0.402 mg/ℓ.

EXISTING STANDARDS AND GUIDELINES

The verified RfD for 2-chlorophenol is 0.005 mg/kg/day or 0.4 mg/day for a 70 kg man (U.S. EPA, 1988), based upon a study by Exon and Koller (1982).

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